

SUMMARY PRODUCT PROFILE FOR PNEUMOCOCCAL CONJUGATE VACCINE (PCV)

Vaccine group¹	Pneumococcal conjugate vaccine (PCV)			
Vaccine type¹	Pneumococcal conjugate vaccine, 10 valent	Pneumococcal conjugate vaccine, 10 valent	Pneumococcal conjugate vaccine, 13 valent	Pneumococcal conjugate vaccine, 13 valent
Serotypes¹	1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F*	1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F*	1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F	1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F
Presentation (doses per container, primary container type, pharmaceutical form)¹	2 dose vial, liquid	4 dose vial, liquid	1 dose vial, liquid	4 dose vial, liquid
Preservative	No	Yes	No	Yes
WHO prequalification status	WHO prequalified	Not yet prequalified, planned for late 2017	WHO prequalified	WHO prequalified
Routine and/or campaign	Routine	Routine	Routine	Routine
Doses per fully immunised person	3	3	3	3
WHO recommended vaccine schedule²	Three doses, in a 3+0 or 2+1 schedule.	Three doses, in a 3+0 or 2+1 schedule.	Three doses, in a 3+0 or 2+1 schedule.	Three doses, in a 3+0 or 2+1 schedule.
Indicative wastage rate⁴	10%	10%	5%	10%
Cold chain volume per dose (cm³)¹	4.8 cm ³	2.4 cm ³	12 cm ³	3 cm ³
Vaccine vial monitor type¹	Type 30	Type 30	Type 30	Type 30
Shelf-life¹	36 months at 2 - 8 °C	36 months at 2 - 8 °C	36 months at 2 - 8 °C	24 months at 2 - 8 °C
2017 price per dose (US\$)³	\$3.05	\$3.05	\$3.30	\$3.10
2017 wastage-adjusted price per fully immunised person*	10.17	10.17	10.42	10.33
Manufacturer¹	GlaxoSmithKline	GlaxoSmithKline	Pfizer	Pfizer
Vaccine trade name	Synflorix	Synflorix	Prevenar 13	Prevenar 13

Handling vials¹	open	WHO recommends that opened vials of this vaccine should be discarded 6 hours after opening or at the end of the immunisation session, whichever comes first.***	Pending confirmation upon WHO prequalification, open vial to be kept for 28 days, as per WHO multi-dose vial policy.	N/A	Open vial to be kept for 28 days, as per WHO multi-dose vial policy.
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1 Source: WHO PQ webpage: WHO updates these webpages as new information on products becomes available. Please refer for these pages for the most up-to-date information.

2 Source: WHO position paper: <http://www.who.int/entity/wer/2010/wer8513.pdf?ua=1>

3 Source: Gavi Price Forecast, June 2016

4 Source: Review of WHO indicative vaccine wastage rate assumptions, 2011

*The European Medicines Agency has provided a positive opinion on cross protection against serotype 19A, a non-vaccine type.

**using WHO indicative wastage rate.

***For more information see:

www.who.int/immunization_standards/vaccine_quality/synflorix_pqnote_2dose_2012/en/

and www.who.int/immunization_standards/vaccine_quality/synflorix_pqnote/en/